CLAIMS

What is claimed is:

Sub A1

1. A method for separating an analyte from a fluid sample and for concentrating the analyte into a volume of elution fluid, the method comprising the steps of:

   a) introducing the sample into a cartridge having:

      i) a sample port;

      ii) a first flow path extending from the sample port;

      iii) an extraction chamber in the first flow path, wherein the extraction chamber contains at least one solid support for capturing the analyte from the sample; and

      iv) a second flow path for eluting the analyte from the extraction chamber, wherein the second flow path passes through the extraction chamber and diverges from the first flow path after passing through the extraction chamber;

   b) forcing the sample to flow through the first flow path, thereby capturing the analyte with the solid support as the sample flows through the extraction chamber, wherein the ratio of the volume of sample forced to flow through the extraction chamber to the volume capacity of the extraction chamber is at least 2:1, and wherein the volume of sample forced to flow through the extraction chamber is at least 0.1 ml; and

   c) forcing an elution fluid to flow through the second flow path, thereby releasing the captured analyte from the solid support into the elution fluid.

2. The method of claim 1, wherein the solid support is selected from the group consisting of filters, beads,

fibers, membranes, glass wool, filter paper, polymers and gels.

3. The method of claim 1, further comprising the step of heating the solid support while forcing the elution fluid to flow through the extraction chamber.

4. The method of claim 3, wherein the solid support is heated to a temperature in the range of 60 to 95°C.

5. The method of claim 1, further comprising the step of forcing a gas to flow through the extraction chamber after the step of forcing the sample to flow through the extraction chamber and prior to the step of forcing the elution fluid to flow through the extraction chamber.

6. The method of claim 1, wherein the ratio of the volume of sample forced to flow through the extraction chamber to the volume capacity of the extraction chamber is at least 10:1.

7. The method of claim 1, wherein the volume of sample forced to flow through the extraction chamber is at least 1 ml.

8. The method of claim 1, wherein the cartridge further comprises a lysing region in the first flow path upstream from the extraction chamber, and the method further comprises the steps of lysing sample components in the lysing region prior to forcing the sample to flow through the extraction chamber.

9. The method of claim 8, wherein the lysing region comprises

a lysing chamber containing a solid phase for capturing the sample components, and wherein the sample components are lysed by:

i) capturing the sample components with the solid phase; and

ii) transferring ultrasonic energy to the sample components using an ultrasonic transducer coupled to a wall of the lysing chamber.

10. The method of claim 9, wherein the solid phase comprises a membrane or filter for capturing the components by size exclusion.

11. The method of claim 9, wherein the solid phase comprises beads for capturing the components by affinity retention or chemical selection.

12. The method of claim 9, wherein the transducer comprises an ultrasonic horn.

13. The method of claim 10, further comprising the step of agitating beads in the lysing chamber to rupture the sample components.

14. The method of claim 1, wherein the second flow path leads to a reagent chamber, and the method further comprises the step of mixing the eluted analyte with a reagent in the reagent chamber.

15. The method of claim 1, wherein the second flow path leads to a reaction chamber, the analyte comprises nucleic acid,

and the method further comprises the steps of amplifying and detecting the nucleic acid in the reaction chamber.

16. The method of claim 1, wherein the cartridge further includes:

a lysing region in the first flow path upstream of the extraction chamber;

a waste chamber in fluid communication with the extraction chamber via the first flow path; and

a reaction chamber in fluid communication with the extraction chamber via the second flow path;

and wherein the method further comprises the steps of:

lysing sample components in the lysing region prior to forcing the sample to flow through the extraction chamber;

forcing the sample to flow into the waste chamber after the sample flows through the extraction chamber;

forcing the eluted analyte to flow into the reaction chamber; and

amplififying or detecting the analyte in the reaction chamber.

17. The method of claim 16, wherein the cartridge further includes a reagent chamber in fluid communication with the extraction chamber and the reaction chamber, and wherein the method further comprises the step of mixing the eluted analyte with a reagent in the reagent chamber prior to amplifying or detecting the analyte in the reaction chamber.

18. A method for separating an analyte from a fluid sample, the method comprising the steps of:

a) introducing the sample into a cartridge having:

i) a sample port;

ii) a first flow path extending from the sample port, wherein the first flow path includes an extraction chamber and a waste chamber downstream of the extraction chamber, the extraction chamber contains at least one solid support for capturing the analyte from the sample, the solid support is selected from the group consisting of filters, beads, fibers, membranes, glass wool, filter paper, polymers and gels, and the cartridge includes means for holding the solid support in the extraction chamber; and

iii) a second flow path for eluting the analyte from the extraction chamber, wherein the second flow path passes through the extraction chamber and diverges from the first flow path after passing through the extraction chamber;

b) forcing the sample to flow through the extraction chamber and into the waste chamber, thereby capturing the analyte with the solid support as the sample flows through the extraction chamber; and

c) eluting the analyte from the extraction chamber by forcing an elution fluid to flow through the extraction chamber while retaining the solid support in the extraction chamber, thereby releasing the analyte from the solid support into the elution fluid.

19. The method of claim 18, further comprising the step of heating the solid support while forcing the elution fluid to flow through the extraction chamber.

20. The method of claim 19, wherein the solid support is heated to a temperature in the range of 60 to 95°C.

21. The method of claim 18, further comprising the step of forcing a gas to flow through the extraction chamber after the step of forcing the sample to flow through the extraction chamber and prior to the step of forcing the elution fluid to flow through the extraction chamber.

22. The method of claim 18, wherein the volume of sample forced to flow through the extraction chamber is at least 0.1 ml.

23. The method of claim 22, wherein the ratio of the volume of sample forced to flow through the extraction chamber to the volume capacity of the extraction chamber is at least 2:1.

24. The method of claim 18, wherein the ratio of the volume of sample forced to flow through the extraction chamber to the volume capacity of the extraction chamber is at least 10:1.

25. The method of claim 18, wherein the volume of sample forced to flow through the extraction chamber is at least 1 ml.

26. The method of claim 18, wherein the cartridge further comprises a lysing region in the first flow path upstream from the extraction chamber, and the method further comprises the steps of lysing sample components in the lysing region prior to forcing the sample to flow through the extraction chamber.

27. The method of claim 26, wherein the lysing region comprises

a lysing chamber containing a solid phase for capturing the sample components, and wherein the sample components are lysed by:

i) capturing the sample components with the solid phase; and

ii) transferring ultrasonic energy to the sample components using an ultrasonic transducer coupled to a wall of the lysing chamber.

28. The method of claim 27, wherein the solid phase comprises a membrane or filter for capturing the components by size exclusion.

29. The method of claim 27, wherein the solid phase comprises beads for capturing the components by affinity retention or chemical selection.

30. The method of claim 27, wherein the transducer comprises an ultrasonic horn.

31. The method of claim 28, further comprising the step of agitating beads in the lysing chamber to rupture the sample components.

32. The method of claim 18, wherein the second flow path leads to a reagent chamber, and the method further comprises the step of mixing the eluted analyte with a reagent in the reagent chamber.

33. The method of claim 18, wherein the second flow path leads to a reaction chamber, the analyte comprises nucleic acid,

and the method further comprises the steps of amplifying and detecting the nucleic acid in the reaction chamber.

34. The method of claim 18, wherein the cartridge further includes:

a lysing region in the first flow path upstream of the extraction chamber;

a waste chamber in fluid communication with the extraction chamber via the first flow path; and

a reaction chamber in fluid communication with the extraction chamber via the second flow path;

and wherein the method further comprises the steps of:

lysing sample components in the lysing region prior to forcing the sample to flow through the extraction chamber;

forcing the sample to flow into the waste chamber after the sample flows through the extraction chamber;

forcing the eluted analyte to flow into the reaction chamber; and

amplififying or detecting the analyte in the reaction chamber.

35. The method of claim 34, wherein the cartridge further includes a reagent chamber in fluid communication with the extraction chamber and the reaction chamber, and wherein the method further comprises the step of mixing the eluted analyte with a reagent in the reagent chamber prior to amplifying or detecting the analyte in the reaction chamber.

36. A method for separating an analyte from a fluid sample, the method comprising the steps of:

a) introducing the sample into a cartridge having:

i) a sample port;

ii) a first flow path extending from the sample port, wherein the first flow path includes a lysing region, at least one flow-through component downstream of the lysing region for capturing the analyte, and a waste chamber downstream of the flow-through component for receiving waste fluid;

iii) a second flow path for eluting the analyte from the flow-through component, wherein the second flow path passes through the flow-through component and diverges from the first flow path after passing through the flow-through component;

b) lysing sample components in the lysing region to release the analyte therefrom;

c) forcing the lysed sample to flow through the flow-through component and into the waste chamber, thereby capturing the analyte with the flow-through component; and

d) eluting the analyte from the flow-through component by forcing an elution fluid to flow along the second flow path.

37. The method of claim 36, wherein the flow-through component comprises an extraction chamber containing at least one solid support, and wherein the analyte is captured by binding the analyte to the solid support.

38. The method of claim 37, further comprising the step of heating the extraction chamber while forcing the elution fluid to flow through the extraction chamber.

39. The method of claim 38, wherein the extraction chamber is heated to a temperature in the range of 60 to 95°C.

40. The method of claim 36, wherein the flow-through component comprises a microfluidic chip having an extraction chamber containing an array of microstructures, the analyte is captured by binding the analyte to the microstructures, and each of the microstructures has an aspect ration of at least 2:1.

41. The method of claim 40, further comprising the step of heating the microstructures while forcing the elution fluid to flow through the extraction chamber.

42. The method of claim 41, wherein the microstructures are heated to a temperature in the range of 60 to 95°C.

43. The method of claim 36, wherein the volume of sample forced to flow through the flow-through components is at least 0.1 ml.

44. The method of claim 43, wherein the flow-through component comprises an extraction chamber through which the sample is forced to flow, and wherein the ratio of the volume of sample forced to flow through the extraction chamber to the volume capacity of the extraction chamber is at least 2:1.

45. The method of claim 44, wherein the ratio of the volume of sample forced to flow through the extraction chamber to the volume capacity of the extraction chamber is at least 10:1.

46. The method of claim 36, wherein the volume of sample forced to flow through the flow-through components is at least 1 ml.

47. The method of claim 36, wherein the lysing region comprises a lysing chamber containing a solid phase for capturing the sample components, and wherein the sample components are lysed by:

i) capturing the sample components with the solid phase; and

ii) transferring ultrasonic energy to the sample components using an ultrasonic transducer directly coupled to a wall of the lysing chamber.

48. The method of claim 47, wherein the solid phase comprises a membrane or filter for capturing the components by size exclusion.

49. The method of claim 47, wherein the solid phase comprises beads for capturing the components by affinity retention or chemical selection.

50. The method of claim 47, wherein the transducer comprises an ultrasonic horn.

51. The method of claim 48, further comprising the step of agitating beads in the lysing chamber to rupture the sample components.

52. The method of claim 36, wherein the second flow path leads to a reagent chamber, and the method further comprises the

step of mixing the eluted analyte with a reagent in the reagent chamber.

53. The method of claim 36, wherein the second flow path leads to a reaction chamber, the analyte comprises nucleic acid, and the method further comprises the steps of amplifying or detecting the nucleic acid in the reaction chamber.

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